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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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Application of: Aberg *et al.*

Application No.: 09/039,260 Art Unit: 1623

Filed: March 16, 1998 Examiner: L. Crane

For: COMPOSITIONS OF DESCARBOETHOXYLORATADINE Attorney Docket No.: 4821-306

## REPLY BRIEF

**Mail Stop Appeal Brief - Patents**
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Pursuant to the provisions of 37 C.F.R. § 1.193(b), Appellants submit herewith a Reply Brief in Response to the Examiner's Answer mailed November 7, 2003 ("the Answer"). A Petition for Extension of time under 37 C.F.R. § 1.136(b) has been submitted on January 6, 2004. In addition, a Supplemental Petition for Extension of Time under 37 C.F.R. § 1.136(b) and a Request for Oral Hearing have been submitted on January 7, 2004.

### Response to Examiner's Grouping of Claims

On pages 3-4 of the Answer, the Examiner objects to Appellants' grouping of claims because Appellants' Groups I and II, and III and IV, are allegedly directed to overlapping subject matter. The Examiner further suggests two groups, which respectively encompass: 1) pharmaceutical compositions comprising DCL and a decongestant; and 2) pharmaceutical compositions comprising DCL and other therapeutic agents. Appellants disagree for the following reasons.

One of the issues on appeal is whether the Examiner properly combined U.S. Patent No. 4,659,716 to Villani *et al.* ("Villani") with Berkow *et al.*, Merck Manual of Diagnosis and Therapy, 16th Ed. (Merck and Co., Rahway, NJ), pp. 324-7 and 3245-7 (1992) ("Berkow") when rejecting claims in Appellants' Groups I and II under 35 U.S.C. § 102(b). As the Examiner himself recognizes in the Answer, claims in Appellants' Group I are "claims wherein DCL is accompanied by a generic 'decongestant' only, and the particular

decongestant 'pseudoephedrine' is not named." Answer, page 9. The Examiner continues by alleging that Villani, "standing alone[,] is a proper anticipatory reference," if applied to the claims in Appellants' Group I. *Id.*

Because the Examiner is forced to rely on different combinations of prior art when addressing the claims in Appellants' Groups I and II, it is apparent that the claims in Groups I and II are patentably distinct. Therefore, Appellants' original definitions of those groups should be accepted.

The claims should also be grouped as in Appellants' Groups III and IV, because the claims in those groups are patentably distinct. As Appellants stated in their Brief on Appeal, claims in Group III are directed to pharmaceutical compositions comprising DCL and non-steroidal anti-inflammatory agents, whereas those in Group IV are directed to pharmaceutical compositions comprising DCL and non-narcotic analgesics. Despite this distinction, the Examiner attempts to place all of the claims in one group by alleging that both types of therapeutic agents belong to a single category of "other therapeutic agents." This assertion is contrary to both law and science. For example, even if pharmaceutical compositions comprising DCL and non-steroidal anti-inflammatory agents were found unpatentable, such a finding would not require a similar finding with regard to pharmaceutical compositions comprising DCL and non-narcotic analgesics.

For the foregoing reasons, Appellants respectfully request that their original grouping of claims be accepted.

## Response to Examiner's Arguments

A. Claims 48, 50, 52-53 and 63-65 Are Not Anticipated by Villani

In the Answer, the Examiner alleges that claims 48, 50, 52-53 and 63-65 are anticipated by Villani alone. Answer, page 9. In response to Appellants' argument that Villani fails to disclose a pharmaceutical compositions comprising from about 0.1 mg to about 5 mg of DCL and an amount of decongestant, the Examiner points to a portion of Villani which discloses the administration of DCL to guinea pigs, and to a portion which discloses a typical dosage regimen for the compounds generically disclosed in Villani. As discussed below, neither portion discloses the range of DCL recited by the pending claims.

In attempting to establish that the specific amounts of DCL recited by the claims are disclosed by Villani, the Examiner extrapolates the dose of DCL used for guinea pigs (*i.e.*, 0.03 mg/kg) to a human weighing 150 pounds. *Id.* Such a manipulation clearly involves the use of hindsight. Moreover, regardless of what that number translates into,

Villani simply does not disclose a pharmaceutical composition comprising an amount of DCL of from about 0.5 mg to about 5 mg, as recited by the claims.[1] Therefore, Appellants respectfully submit that the Examiner's reliance on the portion of Villani that discloses the administration of 0.03 mg/kg DCL to guinea pigs cannot provide a basis for rejecting claims 48, 50, 52-53 and 63-65 under 35 U.S.C. § 102(b).

The Examiner further relies on a portion of Villani which reports that a typical dosage regimen of the compounds it discloses is 10 to 20 mg/day, in two to four divided doses. It is alleged that these doses "clearly fall within the dosage limits of the instant claims." Answer, page 9. Appellants respectfully disagree.

Villani's disclosure could be interpreted to mean that amounts of the genus of compounds it discloses can be administered in a range of 2.5 mg to 10 mg. That range overlaps with the range recited by the claims on appeal. However, when the prior art "discloses a range that ... overlaps ... the claimed range, but no specific examples falling within the claimed range are disclosed," a case by case determination must be made as to whether or not anticipation exists. Manual of Patent Examining Procedure, § 2131.03. This is because in order to be anticipated, the claimed subject matter must be disclosed in the prior art with sufficient specificity. *Id.* No such specificity exists here. The amount of 10 mg to 20 mg disclosed in Villani, in two to four doses a day, is reportedly applicable to every compound belonging to the genus of compounds disclosed in Villani. Villani does not disclose the use of DCL in that amount. Furthermore, when considered in connection with Villani's more general teaching that its compounds can be used in an amount of from 1 mg to 1000 mg, it is clear that Villani does not disclose the amount of DCL recited by the claims with any specificity whatsoever.

In sum, the amount of DCL recited by claims 48, 50, 52-53 and 63-65 is not disclosed by Villani.[2,3] This is evidenced by the Examiner's reliance upon hindsight,

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[1] Villani states that a unit dosage of 0.03 mg/kg of DCL can be used for guinea pigs. Therefore, it is clear that the pharmaceutical composition used in Villani, if there was one, would have contained DCL in a much lower amount than that recited by the claims on appeal.

[2] Appellants note that none of the Examiner's analyses are applicable to the rejection of claim 63. This is because the amounts of DCL disclosed in Villani, even when obtained using the Examiner's manipulation, would be outside the range recited by claim 63. Therefore, regardless of the Examiner's reasoning, the rejection of claim 63 over Villani cannot be maintained.

[3] Claims 64 and 65 do not recite an amount of DCL. Claim 64, which is rejected as allegedly anticipated by the combination of Villani and Berkow, will be discussed in more detail in the section that follows. The Examiner does not provide any arguments as to why claim 65 is anticipated by Villani.

extrapolation, and manipulation of what little information Villani does disclose. Thus, the rejection of claims 48, 50, 52-53 and 63-65 under 35 U.S.C. § 102(b) should be overturned.[4]

B. Claims 54, 61 and 64 Are Not Anticipated by Villani and Berkow

On page 10 of the Answer, the Examiner alleges that identical arguments are applicable to the rejection of claims 54 and 61 under 35 U.S.C. § 102(b). Presumably, the Examiner means that his arguments regarding all limitations but the specific species of decongestant (*i.e.*, pseudoephedrine) recited by the claims 54 and 61 remain the same. With regard to pseudoephedrine, which is not disclosed by Villani, the Examiner relies on Berkow, but alleges that Berkow is only cited to "provide a definition of a specific compound well known in the art to be a 'decongestant'." Answer, page 5.

As discussed in detail in Appellants' Brief on Appeal, the reliance upon Berkow in rejecting claims 54 and 61 under § 102(b) is legally impermissible. It is a well-established principle that the prior art disclosure of a genus does not necessarily anticipate a claim to a species. *See, e.g., Akzo N.V. v. International Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986). In an attempt to overcome this well-established principle, the Examiner is alleging that Berkow is only used to provide a definition of "decongestant." This blatant distortion of caselaw regarding the use of prior art to define a term used in an allegedly anticipatory reference cannot stand. The terms "decongestant" and "pseudoephedrine" are not synonyms. *See, e.g.*, Webster's Third New International Dictionary (Merriam-Webster Inc., Springfield, MA, 1993), pages 587 and 1830 (defining decongestant as "an agent that relieves congestion," and pseudoephedrine as "a poisonous alkaloid C10H15NO occurring with ephedrine and isomeric with it"). Clearly, Berkow is used to provide a specific species of decongestant recited by claims 54 and 61, and thus to provide a limitation missing from the disclosure of Villani. Because Villani alone cannot anticipate claims 54 and 61, rejection of claims 54 and 61 under 35 U.S.C. § 102(b) should be overturned.

With regard to the rejection of claim 64, the Examiner does admit that Villani "does not teach [an aerosol spray]." Answer, page 10. Despite this express admission, the Examiner alleges that claim 64 is nevertheless anticipated because Berkow teaches the use of nasal sprays in the treatment of perennial rhinitis. *Id.* Here again, the Examiner is relying on

[4] It should be noted that even if Villani did disclose an amount of DCL that falls within the range recited by the claims on appeal, that amount is not necessarily applicable to a pharmaceutical composition comprising both DCL and a decongestant. This is because there is no disclosure in Villani that the same amount of the genus of compounds it discloses can be used when those compounds are used in combination with another therapeutic agent.

the combination of Villani and Berkow. Therefore, the rejection of claim 64 under 35 U.S.C. § 102(b) should also be overturned.

C. Claims 48, 50, 52-53 and 63-65 Are Not Obvious

The Examiner's response to Appellants' arguments regarding claims 48, 50, 52-53 and 63 is summarized as follows: 1) Appellants failed to argue, and thus conceded, lack of motivation or lack of expectation of success provided by Villani and Berkow; 2) although Appellants did argue that all of the limitations of the claims are not found in Villani, the Examiner disagrees because of the reasons provided for the rejections under 35 U.S.C. § 102(b) (*i.e.*, the amounts of DCL recited by the claims 48, 50, 52-53 and 63-65 is disclosed in Villani); and 3) Villani discloses all of the limitations recited by claims 48, 50, 52-53 and 63. Answer, pages 10-11. Appellants disagree with each of these allegations.

First, the Examiner appears to have misunderstood arguments made in Appellants' Brief on Appeal. Appellants argued that Villani, by disclosing a large genus of compounds that can be used in an amount of from 1 mg to 1000 mg, does not motivate one of ordinary skill in the art to single out DCL and use it in the low amount recited by claims 48, 50, 52-53 and 63. Brief on Appeal dated August 15, 2003, page 14. In fact, Villani teaches away from the claimed invention because the only concrete examples of pharmaceutical compositions it provides use a large amount, *i.e.*, 100 mg or 500 mg, of the active ingredient. *Id.* Moreover, since neither Villani nor Berkow discloses the use of DCL in an amount much lower than 100 or 500 mg, their combination does not disclose each and every limitation of the claims on appeal. *Id.*

All of these arguments were clearly made, despite the Examiner failure to recognize them. The Examiner further mischaracterizes Appellants' arguments by arguing that the amount of DCL recited by claims 48, 50, 52-53 and 63 is disclosed in Villani if certain amounts disclosed in Villani are manipulated according to the Examiner's arbitrary assumptions.[5] As discussed above, this is not the case. Therefore, the Examiner's rejection of claims 48, 50, 52-53 and 63 should be reversed.[6]

The Examiner further alleges that claim 64 is obvious because Berkow –unlike Villani– discloses nasal sprays. Answer, page 11. However, the combination of Villani and

[5] See Section A, above.

[6] Again, regardless of how one manipulates the numbers disclosed in Villani, Villani does not disclose 0.2 mg to 1 mg of DCL as recited by claim 63. Since the Examiner fails to provide any reasons as to why claim 63 is obvious, Appellants respectfully submit that claim 63 is not obvious over the references cited by the Examiner.

Berkow would not have motivated one of ordinary skill in the art to make and use an aerosol spray comprising DCL and a decongestant. This is because Villani, while disclosing a genus of compounds that includes DCL, fails to disclose or suggest an aerosol spray containing DCL, much less an aerosol spray containing DCL and a decongestant. On the other hand, Berkow discloses that nasal sprays of antihistamines in general can be used in treating certain types of perennial rhinitis. Berkow does not disclose or suggest that DCL, much less DCL in combination with a decongestant, can or should be administered as a nasal spray.

In fact, Berkow actually teaches away from an aerosol spray containing DCL and a decongestant. This is because Berkow teaches that for the types of hypersensitivity for which the use of nasal sprays may be beneficial, patients should be advised "to avoid topical decongestants, which ... may aggravate or perpetuate chronic rhinitis." Berkow, page 327, under Treatment (of perennial rhinitis). At a minimum, Berkow clearly suggests that combining nasal antihistamines with decongestants causes problems. Therefore, it is clear that those of ordinary skill in the art would have been discouraged from using nasal sprays of an antihistamine in combination with a decongestant. As such, Berkow would have done nothing to motivate one of ordinary skill in the art to make and use nasal sprays of an antihistamine and a decongestant, much less of DCL and a decongestant. *See C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998), citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

It is also alleged that claim 65 is obvious, because elixir, "aka 'liquid pharmaceutical composition'," is disclosed in Villani. Answer, page 11. However, the equating the term "elixir" with "liquid pharmaceutical composition" is entirely contrary to law and science because elixir is not the only liquid pharmaceutical composition known in the art. Elixir is a sweetened solution of water and alcohol, and is only one of many types of liquid pharmaceutical composition known in the art. *See, e.g.*, Remington's Pharmaceutical Sciences (Mack Publishing Co., Easton, PA, 1980), p.p. 1225-1267. In this regard, Villani fails to disclose all of the limitations recited by claim 65.

Villani also fails to provide the required motivation to specifically make and use an elixir comprising DCL and a decongestant. This is because Villani, by generically disclosing "liquid pharmaceutical composition," which may contain the genus of compounds it discloses, does nothing to teach or suggest to one of ordinary skill in the art that it is desirable to make and use an elixir containing DCL and a decongestant. Therefore, it is clear that claim 65 would not have been obvious in view of Villani's generic disclosure that the genus of compounds it discloses can be in a form of a generic "liquid pharmaceutical

composition." Therefore, the rejection of claim 65, like those of claims 48, 50, 52-53 and 63, should be reversed.

D. Claims 54 and 61 Are Not Obvious

The Examiner responds to Appellants' arguments regarding claims 54 and 61 by referring to the arguments he made for claims 48, 50, 52-53 and 63. He provides no specific reasons as to why the recitation of pseudoephedrine would have been obvious in light of Villani and Berkow. Presumably, the Examiner believes that Villani, in combination with Berkow, discloses all of the limitations of claims 54 and 61.

As discussed above, Villani does not disclose the amounts of DCL recited by claims 54 and 61. For this reason alone, the rejection of these claims as allegedly obvious should be reversed. Other reasons exist, however, as to why the rejection of these claims should be overturned. For example, Berkow is but one of many references that disclose various species of decongestants. Therefore, unless Villani or Berkow provides a specific motivation to combine DCL and pseudoephedrine, claims 54 and 61 cannot be rejected as obvious over the combination of these references. Neither reference provides such a motivation. In fact, Berkow teaches away from the combination of DCL and a decongestant in certain types of rhinitis.[7] Thus, the Examiner's use of Berkow to provide the missing element of pseudoephedrine is based entirely on impermissible hindsight. *See C.R. Bard Inc.*, 157 F.3d 1340 at 1352.

For the foregoing reasons, the Examiner's rejection of claims 54 and 61 under 35 U.S.C. § 103 should be reversed.

E. Claims 55-61 and 66-68 Are Not Obvious

The Examiner's rejection of claims 55-61 and 66-68 revolves around the proposition that Villani, by disclosing a genus of compounds that can reportedly be used in combination with "other therapeutic agents," would have motivated one of ordinary skill in the art to combine, in a pharmaceutical composition, the specific compound DCL and either an anti-inflammatory agent or a non-steroidal analgesic. The Examiner alleges that the claims are obvious over the combination of Villani and Gennaro *et al.*, Reminton's Pharmaceutical Sciences, 18th Ed. (Philadelphia College of Pharmacy and Science), pp. 1097-1130 (1990) ("Gennaro"), which discloses, among others, the specific therapeutic agents recited by the claims. Appellants disagree.

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[7] *See* Section C, above.

The Examiner fails to explain what it is about Villani that would have motivated those of ordinary skill in the art to seek out an anti-inflammatory agent or a non-steroidal analgesic to be used in combination with DCL. Villani, by merely stating that the genus of compounds it discloses can be used in combination with "other therapeutic agents," and by not limiting what those other therapeutic agents may be, provides those of ordinary skill in the art with absolutely no direction or aid in seeking out such agents. Since a large, if not infinite, number of "other therapeutic agents" is available and known in the art, the combination of DCL with any therapeutic agents would necessarily present an "obvious to try" situation, absent a suggestion in Villani or Gennaro that the combination of DCL and a particular therapeutic agent would be particularly effective. Based on these facts, it is clear that the combination of Villani and Gennaro is based entirely on the use of impermissible hindsight. Brief on Appeal filed August 15, 2003, page 22.

The Examiner disagrees, arguing that Gennaro "does not have unlimited selection of other 'therapeutic agents' which may be combined with an antihistamine such as DCL." Answer, pages 13-14. This statements completely misses the mark. The Examiner is apparently assuming that Gennaro discloses the whole universe of "other therapeutic agents" available, which is certainly not the case. Instead of relying on hindsight, the Examiner should have inquired as to whether there is any specific suggestion in Villani or Gennaro that certain specific analgesics and antipyretics disclosed in Gennaro can be advantageously combined with the antihistamine DCL. Because such a suggestion does not exist, the combination of Villani and Gennaro does not render the claims on appeal obvious. Therefore, the rejection of claims 55-61 and 66-68 under 35 U.S.C. § 103 should be reversed.

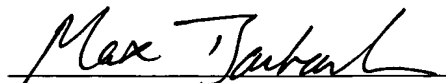
## Conclusion

For the reasons stated above and in Appellants' Brief on Appeal, Appellants submit that the rejections of claims 48, 50, 52-61 and 63-68 are in error, and respectfully request the Board to overturn the rejections.

No fee is believed due for the submission of this Reply Brief. If any fees are required, however, please charge such fees to Deposit Account No. 16-1150.

Respectfully Submitted,

Date: February 9, 2004



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decongestant 'pseudoephedrine' is not named." Answer, page 9. The Examiner continues by alleging that Villani, "standing alone[,] is a proper anticipatory reference," if applied to the claims in Appellants' Group I. *Id.*

Because the Examiner is forced to rely on different combinations of prior art when addressing the claims in Appellants' Groups I and II, it is apparent that the claims in Groups I and II are patentably distinct. Therefore, Appellants' original definitions of those groups should be accepted.

The claims should also be grouped as in Appellants' Groups III and IV, because the claims in those groups are patentably distinct. As Appellants stated in their Brief on Appeal, claims in Group III are directed to pharmaceutical compositions comprising DCL and non-steroidal anti-inflammatory agents, whereas those in Group IV are directed to pharmaceutical compositions comprising DCL and non-narcotic analgesics. Despite this distinction, the Examiner attempts to place all of the claims in one group by alleging that both types of therapeutic agents belong to a single category of "other therapeutic agents." This assertion is contrary to both law and science. For example, even if pharmaceutical compositions comprising DCL and non-steroidal anti-inflammatory agents were found unpatentable, such a finding would not require a similar finding with regard to pharmaceutical compositions comprising DCL and non-narcotic analgesics.

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In attempting to establish that the specific amounts of DCL recited by the claims are disclosed by Villani, the Examiner extrapolates the dose of DCL used for guinea pigs (*i.e.*, 0.03 mg/kg) to a human weighing 150 pounds. *Id.* Such a manipulation clearly involves the use of hindsight. Moreover, regardless of what that number translates into,

Villani simply does not disclose a pharmaceutical composition comprising an amount of DCL of from about 0.5 mg to about 5 mg, as recited by the claims.[1] Therefore, Appellants respectfully submit that the Examiner's reliance on the portion of Villani that discloses the administration of 0.03 mg/kg DCL to guinea pigs cannot provide a basis for rejecting claims 48, 50, 52-53 and 63-65 under 35 U.S.C. § 102(b).

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In sum, the amount of DCL recited by claims 48, 50, 52-53 and 63-65 is not disclosed by Villani.[2,3] This is evidenced by the Examiner's reliance upon hindsight,

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[3] Claims 64 and 65 do not recite an amount of DCL. Claim 64, which is rejected as allegedly anticipated by the combination of Villani and Berkow, will be discussed in more detail in the section that follows. The Examiner does not provide any arguments as to why claim 65 is anticipated by Villani.

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C. Claims 48, 50, 52-53 and 63-65 Are Not Obvious

The Examiner's response to Appellants' arguments regarding claims 48, 50, 52-53 and 63 is summarized as follows: 1) Appellants failed to argue, and thus conceded, lack of motivation or lack of expectation of success provided by Villani and Berkow; 2) although Appellants did argue that all of the limitations of the claims are not found in Villani, the Examiner disagrees because of the reasons provided for the rejections under 35 U.S.C. § 102(b) (*i.e.*, the amounts of DCL recited by the claims 48, 50, 52-53 and 63-65 is disclosed in Villani); and 3) Villani discloses all of the limitations recited by claims 48, 50, 52-53 and 63. Answer, pages 10-11. Appellants disagree with each of these allegations.

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The Examiner further alleges that claim 64 is obvious because Berkow –unlike Villani– discloses nasal sprays. Answer, page 11. However, the combination of Villani and

[5] See Section A, above.

[6] Again, regardless of how one manipulates the numbers disclosed in Villani, Villani does not disclose 0.2 mg to 1 mg of DCL as recited by claim 63. Since the Examiner fails to provide any reasons as to why claim 63 is obvious, Appellants respectfully submit that claim 63 is not obvious over the references cited by the Examiner.

Berkow would not have motivated one of ordinary skill in the art to make and use an aerosol spray comprising DCL and a decongestant. This is because Villani, while disclosing a genus of compounds that includes DCL, fails to disclose or suggest an aerosol spray containing DCL, much less an aerosol spray containing DCL and a decongestant. On the other hand, Berkow discloses that nasal sprays of antihistamines in general can be used in treating certain types of perennial rhinitis. Berkow does not disclose or suggest that DCL, much less DCL in combination with a decongestant, can or should be administered as a nasal spray.

In fact, Berkow actually teaches away from an aerosol spray containing DCL and a decongestant. This is because Berkow teaches that for the types of hypersensitivity for which the use of nasal sprays may be beneficial, patients should be advised "to avoid topical decongestants, which ... may aggravate or perpetuate chronic rhinitis." Berkow, page 327, under Treatment (of perennial rhinitis). At a minimum, Berkow clearly suggests that combining nasal antihistamines with decongestants causes problems. Therefore, it is clear that those of ordinary skill in the art would have been discouraged from using nasal sprays of an antihistamine in combination with a decongestant. As such, Berkow would have done nothing to motivate one of ordinary skill in the art to make and use nasal sprays of an antihistamine and a decongestant, much less of DCL and a decongestant. *See C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998), citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

It is also alleged that claim 65 is obvious, because elixir, "aka 'liquid pharmaceutical composition'," is disclosed in Villani. Answer, page 11. However, the equating the term "elixir" with "liquid pharmaceutical composition" is entirely contrary to law and science because elixir is not the only liquid pharmaceutical composition known in the art. Elixir is a sweetened solution of water and alcohol, and is only one of many types of liquid pharmaceutical composition known in the art. *See, e.g.*, Remington's Pharmaceutical Sciences (Mack Publishing Co., Easton, PA, 1980), p.p. 1225-1267. In this regard, Villani fails to disclose all of the limitations recited by claim 65.

Villani also fails to provide the required motivation to specifically make and use an elixir comprising DCL and a decongestant. This is because Villani, by generically disclosing "liquid pharmaceutical composition," which may contain the genus of compounds it discloses, does nothing to teach or suggest to one of ordinary skill in the art that it is desirable to make and use an elixir containing DCL and a decongestant. Therefore, it is clear that claim 65 would not have been obvious in view of Villani's generic disclosure that the genus of compounds it discloses can be in a form of a generic "liquid pharmaceutical

composition." Therefore, the rejection of claim 65, like those of claims 48, 50, 52-53 and 63, should be reversed.

D. Claims 54 and 61 Are Not Obvious

The Examiner responds to Appellants' arguments regarding claims 54 and 61 by referring to the arguments he made for claims 48, 50, 52-53 and 63. He provides no specific reasons as to why the recitation of pseudoephedrine would have been obvious in light of Villani and Berkow. Presumably, the Examiner believes that Villani, in combination with Berkow, discloses all of the limitations of claims 54 and 61.

As discussed above, Villani does not disclose the amounts of DCL recited by claims 54 and 61. For this reason alone, the rejection of these claims as allegedly obvious should be reversed. Other reasons exist, however, as to why the rejection of these claims should be overturned. For example, Berkow is but one of many references that disclose various species of decongestants. Therefore, unless Villani or Berkow provides a specific motivation to combine DCL and pseudoephedrine, claims 54 and 61 cannot be rejected as obvious over the combination of these references. Neither reference provides such a motivation. In fact, Berkow teaches away from the combination of DCL and a decongestant in certain types of rhinitis.[7] Thus, the Examiner's use of Berkow to provide the missing element of pseudoephedrine is based entirely on impermissible hindsight. *See C.R. Bard Inc.*, 157 F.3d 1340 at 1352.

For the foregoing reasons, the Examiner's rejection of claims 54 and 61 under 35 U.S.C. § 103 should be reversed.

E. Claims 55-61 and 66-68 Are Not Obvious

The Examiner's rejection of claims 55-61 and 66-68 revolves around the proposition that Villani, by disclosing a genus of compounds that can reportedly be used in combination with "other therapeutic agents," would have motivated one of ordinary skill in the art to combine, in a pharmaceutical composition, the specific compound DCL and either an anti-inflammatory agent or a non-steroidal analgesic. The Examiner alleges that the claims are obvious over the combination of Villani and Gennaro *et al.*, Reminton's Pharmaceutical Sciences, 18th Ed. (Philadelphia College of Pharmacy and Science), pp. 1097-1130 (1990) ("Gennaro"), which discloses, among others, the specific therapeutic agents recited by the claims. Appellants disagree.

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[7] *See* Section C, above.

The Examiner fails to explain what it is about Villani that would have motivated those of ordinary skill in the art to seek out an anti-inflammatory agent or a non-steroidal analgesic to be used in combination with DCL. Villani, by merely stating that the genus of compounds it discloses can be used in combination with "other therapeutic agents," and by not limiting what those other therapeutic agents may be, provides those of ordinary skill in the art with absolutely no direction or aid in seeking out such agents. Since a large, if not infinite, number of "other therapeutic agents" is available and known in the art, the combination of DCL with any therapeutic agents would necessarily present an "obvious to try" situation, absent a suggestion in Villani or Gennaro that the combination of DCL and a particular therapeutic agent would be particularly effective. Based on these facts, it is clear that the combination of Villani and Gennaro is based entirely on the use of impermissible hindsight. Brief on Appeal filed August 15, 2003, page 22.

The Examiner disagrees, arguing that Gennaro "does not have unlimited selection of other 'therapeutic agents' which may be combined with an antihistamine such as DCL." Answer, pages 13-14. This statements completely misses the mark. The Examiner is apparently assuming that Gennaro discloses the whole universe of "other therapeutic agents" available, which is certainly not the case. Instead of relying on hindsight, the Examiner should have inquired as to whether there is any specific suggestion in Villani or Gennaro that certain specific analgesics and antipyretics disclosed in Gennaro can be advantageously combined with the antihistamine DCL. Because such a suggestion does not exist, the combination of Villani and Gennaro does not render the claims on appeal obvious. Therefore, the rejection of claims 55-61 and 66-68 under 35 U.S.C. § 103 should be reversed.

## Conclusion

For the reasons stated above and in Appellants' Brief on Appeal, Appellants submit that the rejections of claims 48, 50, 52-61 and 63-68 are in error, and respectfully request the Board to overturn the rejections.

No fee is believed due for the submission of this Reply Brief. If any fees are required, however, please charge such fees to Deposit Account No. 16-1150.

Respectfully Submitted,

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